



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

|                             |   |                        |
|-----------------------------|---|------------------------|
| re Application of:          | ) | Art Unit: 1648         |
| CLASSEN, John Barthelow     | ) | Examiner: PARK, H.     |
| Serial No.: 09/660,584      | ) | Washington, D.C.       |
| Filed: September 12, 2000   | ) | April 7, 2004          |
| For: METHOD AND COMPOSITION | ) | Docket No.: CLASSEN=1D |
| FOR AN EARLY VACCINE TO     | ) | Confirmation No.: 2284 |
| PROTECT AGAINST BOTH...     | ) |                        |

INFORMATION DISCLOSURE STATEMENT [IDS]

U.S. Patent and Trademark Office  
2011 South Clark Place <sup>IP</sup>  
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Crystal Plaza Two, Lobby, Room 1B03  
Arlington, Virginia 22202

S i r :

This Information Disclosure Statement is submitted in accordance with 37 C.F.R. 1.97, 1.98, and it is requested that the information set forth in this statement and in the listed documents be considered during the pendency of the above-identified application, and any other application relying on the filing date of the above-identified application or cross-referencing it as a related application.

1. This IDS should be considered, in accordance with 37 C.F.R. 1.97, as it is filed:

[ ] A. within three months of the filing date of the above-identified national application or within three months of the entry into the national stage of the above-identified international application. See 37 CFR 1.97(b)(1) and (3).

[ ] B. before the mailing date of a first office action on the merits. See 37 CFR 1.97(b).

[X] C. after (A) and (B) above, but before final rejection or allowance, and Applicants have made the necessary certification (box "i" below) or paid the necessary fee (box "ii" below). See 37 CFR 1.97(c)(2).

[ ] i. Counsel certifies that, upon information and belief, each item of information listed herein was

either (a) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (b) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[X] ii. Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p), presently believed to be \$180, is attached.

[ ] D. after (A), (B) and (C) above, but before payment of the issue fee. Applicant petitions under 37 C.F.R. 1.97(d) for consideration of this IDS. A Credit Card Payment Form, PTO-2038, authorizing payment for the fee set forth in 1.17(p)(1), presently believed to be \$180 is attached. Counsel certifies that, upon information and belief, each item of information listed herein was either (i) cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this IDS or (ii) was not cited in a communication from a foreign patent office in a counterpart foreign application and was not known to any individual designated in 1.56(c) more than three months prior to the filing of this IDS.

[ ] E. As a submission in accordance with the transitional procedure for limited examination after final rejection pursuant to 37 CFR §1.129(a). Pursuant to MPEP §706.07(g), page 700-66, col. 2 (August 2001), this IDS is treated as if filed with a period set forth in 37 CFR §1.97(b) and considered without the petition and petition fee required by 1.97(d).

[ ] F. As a submission with or after a request for continued examination under CFR §1.114, and before the mailing of a first office action on the RCE. See 37 CFR §1.97(b)(4).

2. In accordance with 37 C.F.R. 1.98, this IDS includes a list (e.g., form PTO-1449) of all patents, publications, or

other information submitted for consideration by the office, either incorporated into this IDS or as an attachment hereto. A copy of each document is attached, except as explained below.

[ ] While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is "encouraged"). Counsel has used a list provided to him by Applicants, and not transferred the information to a PTO-1449, to avoid the risk of any inadvertent error in transferring the information.

[ ] A. Documents \_\_\_\_\_ are deemed substantially cumulative to documents \_\_\_\_\_, and, in accordance with 1.98(c), only a copy of each of the latter documents is enclosed.

[ ] B. Certain documents were previously cited by or submitted to the Office in the following prior application(s), which are relied upon under 35 U.S.C. 120:

[insert serial number/filing date]

Applicants identify these documents by attaching hereto copies of the form PTO-892s and PTO-1449s from the files of the prior applications or a fresh PTO-1449 listing these documents, and request that they be considered and made of record in accordance with 1.98(d). Per 37 CFR 1.98(d), copies of these documents need not be filed in this application. If copies of any of these documents cannot be found in the files of the prior applications, the Examiner is requested to so notify counsel before taking action in this case, so replacement copies can be submitted. While an IDS filed under §1.97 must contain a "list of all patents, publications or other information submitted for consideration by the Office", see §1.98(a) (1), the only requirement for the list is that it provide the information set forth in §1.98(b). There is no requirement that a form PTO-1449 be used (MPEP §609 merely says that use of this form is

"encouraged") and no prohibition on submitting a copy of a form PTO-1449 or form PTO-892 from a prior case. Indeed, the re-use of such forms is desirable as it avoids error in transferring the information, and evidences that the reference was considered in a prior application. A previously accepted PTO-1449, or an examiner-prepared PTO-892, necessarily complies with §1.98(b).

☐ C. Document(s) \_\_\_\_\_ is (are) U.S. patent(s) and/or published application(s). As this is a U.S. application filed after June 30, 2003, or an entry into national stage under 35 USC §371 after June 30, 2003, the requirement to file copies of such U.S. patents or published applications has been waived. (Office of Patent Legal Administration - Pre O.G. Notice of July 11, 2003).

☐ 3. Documents \_\_\_\_\_ are not in the English language. In accordance with 1.98(a)(3), Applicants state:

☐ documents \_\_\_\_\_ already contain an English language abstract, summary or claim set.

☐ a publicly available abstract is attached to each of documents \_\_\_\_, and the source of each abstract is indicated thereon.

☐ documents \_\_\_\_ are patents or published patent applications for which counterpart English language patents or patent applications exist, and are enclosed, as follows:

| <u>Foreign Lang. Doc.#</u> | <u>English Lang. Doc.#</u> |
|----------------------------|----------------------------|
| [insert]                   | [insert]                   |

☐ applicants have prepared an English translation of at least the pertinent portions of documents \_\_\_\_\_, and copies are attached.

☐ A concise explanation of the relevance of documents \_\_\_\_\_ is found in the attached search report from the \_\_\_\_\_ Patent Office (see reply to Comment 68 in the preamble to the final rules; 1135 OG 13 at 20).

☐ A concise explanation of the relevance of documents \_\_\_\_\_ is set forth as follows:

[Insert concise explanation of relevance]

4. No explanation of relevance is necessary for documents in the English language (see reply to Comments 67 and 68 in the preamble to the final rules; 1135 OG 13 at 20).

5. If the month of publication of a nonpatent reference is not stated, it is because it is not apparent from review of the reference. If requested to do so by the Examiner, Applicants will attempt to locate and write to the publisher.

If the publication date of a cited document is set forth only as a publication year, and that year is prior to the year of filing or, if priority is claimed, year of priority of this application, then the particular month of publication is not in issue. Likewise if that publication year is after the year of filing of this application, the month of publication is not in issue.

If the date of publication of a nonpatent reference is stated, then, except as explained below, it is the nominal date stated in the reference, or in a larger document (journal or book) from which the reference was extracted. Applicants reserve the right to challenge this date by contacting the publisher to determine the actual shipment date, or by contacting recipients to determine the receipt dates.

6. Other information being provided for the examiner's consideration follows:

[insert other information]

7. In accordance with 37 C.F.R. 1.97(g) and (h), the filing of this IDS should not be construed as a representation that a search has been made or that information cited is, or is considered to be, material to patentability as defined in §1.56 (b), or that any cited document listed or attached is (or constitutes) prior art. Unless otherwise indicated, the date of publication indicated for an item is taken from the face of the item and Applicant reserves the right to prove that the date of publication is in fact different.

8. The Commissioner is hereby authorized and requested to

USSN - 09/660,584

charge any additional fees which may be required in connection with this paper or credit any overpayment to Deposit Account No. 02-4035.

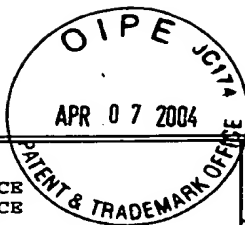
Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By: 

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FORM PTO-1449  
U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

ATTY DOCKET NO: CLASSEN=1D

SERIAL NO: 09/660,584

LIST OF DOCUMENTS CITED BY APPLICANT

APPLICANT: CLASSEN, John Barthelow

FILING DATE: September 12, 2000

GROUP: 1648

U.S. PATENT DOCUMENTS (include at least patentee, patent number and issue date)

| EXAMINER<br>INITIAL |    | DOCUMENT NUMBER |   |   |   |   |   |   | DATE      | PATENTEE | CLASS | SUB-<br>CLASS | FILING DATE<br>IF APPROP. |
|---------------------|----|-----------------|---|---|---|---|---|---|-----------|----------|-------|---------------|---------------------------|
|                     | P1 | 6               | 4 | 2 | 0 | 1 | 3 | 9 | 16JUL2002 | CLASSEN  |       |               |                           |
|                     | P2 | 5               | 7 | 2 | 8 | 3 | 8 | 5 | 17MAR1998 | CLASSEN  |       |               |                           |
|                     | P3 | 5               | 7 | 2 | 3 | 2 | 8 | 3 | 03MAR1998 | CLASSEN  |       |               |                           |

FOREIGN PATENT DOCUMENTS (include at least document number, publication date and country)

|  |  | DOCUMENT NUMBER |  |  |  |  |  |  | DATE | COUNTRY | CLASS | SUB-<br>CLASS | TRANSLATION<br>YES/NO |
|--|--|-----------------|--|--|--|--|--|--|------|---------|-------|---------------|-----------------------|
|  |  |                 |  |  |  |  |  |  |      |         |       |               |                       |

OTHER DOCUMENTS (include author, title, name of publication, volume, pages & date of publication)

|  |    |  |
|--|----|--|
|  | KB | Institute of Medicine, "The Anthrax Vaccine: Is it safe? Does it work?", pp. 1, 3, 136-139, 160-164, 166-170, 246-8, (March 2002).   |
|  | KC | YANG, et al., "Childhood Diabetes in China: Enormous variation by place and ethnic group", <u>DIABETES CARE</u> , vol. 21, no. 4, pgs. 525-9, April 1998.  |
|  | KD | SANJEEVI, et al., "BCG Vaccination and GAD65 and IA-2 Autoantibodies in Autoimmune Diabetes in Southern India", <u>ANN. NY. ACAD. SCI.</u> , vol. 958:, pgs. 293-296, 2002.  |
|  | KE | CLASSEN, et al., "The Safety of Military Immunization and the Risk of Insulin-Dependent Diabetes", <u>CLINICAL PRACTICE OF ALTERNATIVE MEDICINE</u> , vol. 2, no. 4, pgs. 247-252, 2001.   |
|  | KF | KARVONEN, et al., "Incidence of Childhood Type 1 Diabetes Worldwide", <u>DIABETES CARE</u> , vol. 23, no. 10, pgs. 1516-1526, October 2000.  |
|  | KG | DESTEFANO, et al., "Childhood Vaccinations, Vaccination Timing, and Risk of Type 1 Diabetes Mellitus", <u>PEDIATRICS</u> , vol. 108, no. 6, pgs. 1-5, December 2001.   |
|  | KH | CLASSEN and CLASSEN, "Vaccines and the risk of insulin-dependent diabetes (IDDM): potential mechanism of action", <u>MEDICAL HYPOTHESES</u> , vol. 57(5), pgs. 532-538, 2001.  |
|  | KI | CLASSEN and CLASSEN, "Clustering of Cases of Insulin Dependent Diabetes (IDDM) Occurring Three Years After Hemophilus Influenza B (HiB) Immunization Support Causal Relationship Between Immunization and IDDM", <u>AUTOIMMUNITY</u> , vol. 35, pgs. 247-253, 2002.  |
|  | KJ | WAHLBERG, et al., "Vaccinations May Induce Diabetes-Related Autoantibodies in One-Year-Old Children", <u>ANN. N.Y. ACAD. SCI.</u> , vol. 1005, pgs. 404-408, 2003.   |
|  | KK | DESTEFANO, et al., "Childhood vaccinations and risk of asthma", <u>PEDIATR. INFECT. DIS. J.</u> , vol. 21, no. 6, pgs. 498-504, 2002.  |
|  | KL | RIMINTON, et al., "Dermal Enhancement: Bacterial Products on Intact Skin Induce and Augment Organ-Specific Autoimmune Disease", <u>THE JOURNAL OF IMMUNOLOGY</u> , vol. 172, pgs. 302-309, 2004  |
|  | KM | CLASSEN, "Immunization with BCG vaccine starting after age 1 is associated with increased risk of IDDM in Quebec", (unpublished reanalysis of Parent (1997)).  |
|  | KN | CLASSEN, "Vaccines modulate IDDM", <u>DIABETOLOGIA</u> , 39:500-501 (1996).  |
|  | KO | M-M-R II, vaccine Physicians Package Insert pp. 7 & 9 (1999).  |
|  | KP | CLASSEN, et al, "Clustering of Cases of Type 1 Diabetes Mellitus Occurring 2-4 Years After Vaccination is Consistent with Clustering After Infections and Progression of Type 1 Diabetes Mellitus in Autoantibody Positive Individuals", <u>JOURNAL OF PEDIATRIC ENDOCRINOLOGY &amp; METABOLISM</u> 16:495-508 (2003). |

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if reference considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re Application of:       | ) | Art Unit: 1648         |
|                             | ) |                        |
| CLASSEN, John Barthelow     | ) | Examiner: PARK, H.     |
|                             | ) |                        |
| Serial No.: 09/660,584      | ) | Washington, D.C.       |
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| Filed: September 12, 2000   | ) | April 7, 2004          |
|                             | ) |                        |
| For: METHOD AND COMPOSITION | ) | Docket No.: CLASSEN=1D |
| FOR AN EARLY VACCINE TO     | ) |                        |
| PROTECT AGAINST BOTH...     | ) | Confirmation No.: 2284 |

RESPONSE UNDER RULE 1.115

U.S. Patent and Trademark Office  
2011 South Clark Place  
Customer Window  
Crystal Plaza Two, Lobby, Room 1B03  
Arlington, Virginia 22202

S i r :

In response to the March 24, 2004 office action, please enter these remarks, and the enclosed terminal disclaimer.

1. The sole issue in this case relates to the rejection of claims 156 and 192-403 for obviousness-type double patenting over claims 1-113 of USP 6,638,739.

Without conceding the propriety of this rejection, Applicant has chosen to overcome it by filing a terminal disclaimer. Since this application is post-GATT, its expiration date would (absent patent term adjustment) be the same as that of the post-GATT '139 patent, as both claim the same earliest U.S. filing date. Hence, Applicant has no reason to refuse to execute a terminal disclaimer.

For similar reasons, the terminal disclaimer refers also to applicants' prior patents (6,420,139, 5,723,283 and 5,728,385). In the prosecution of the '739 patent (Classen=1E), we filed a terminal disclaimer over the '139 patent. The '283 and '385 patents are pre-GATT patents expiring later than the '139 patent. Hence, it seemed prudent to include them as reference patents for the terminal disclaimer, as it would not alter the instant



expiration date, and it would prevent the issue from arising in litigation.

2. The Examiner's attention is respectfully directed to the PTO-1449s and PTO-892s submitted on September 12, 2000 with the application as filed, and referred to in Section 6 of the transmittal letter filed that day.

Reviewing those papers, they were

- (1) PTO-892 attached to paper 11 in 08/591,651 (1 p.)
- (2) PTO-892 attached to paper 7 in 08/591,651 (3 pp.)
- (3) PTO-1449 listing refs AL, AM in 08/591,651 (1 p.)
- (4) PTO-1449 listing refs 1-37 in 08/591,651 (3 pp.)
- (5) PTO-892 listing refs A-D, R, S in 08/104,529 (1 p.)
- (6) PTO-892 attached to paper 14 in 08/104,529 (1 p.)
- (7) PTO-1449 listing refs AA, AB, AL-CN in 08/104,529 (4 pp.)

The office action mailed March 24, 2004 neither supplies (re)initialed copies of these listings, nor gives any reason for refusing to consider them.

However, in counterpart application 10/124,363 (our docket Classen=1E), the present examiner considered these references on September 30, 2002, as indicated in the attachment to the October 2, 2002 action therein.

It is respectfully requested that the Examiner consider these references with respect to this case, and acknowledge this by appropriately initialing lists (1)-(7) above.

We recognize that these lists (1)-(7) may have been misplaced by the USPTO. Consequently, to expedite prosecution, we enclose replacement copies.

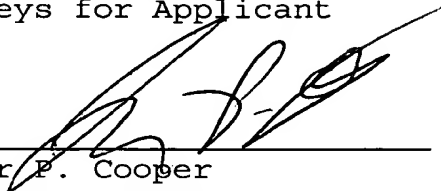
3. Applicants are also filing, on even date herewith, an IDS enclosing a PTO-1449 which lists (1) three Classen patents (the '739, '283, and '385 patents), (2) certain references cited but not considered in Serial No. 08/591,651 (Classen=1A), and

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(3) three additional recent references.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.  
Attorneys for Applicant

By:   
Iver P. Cooper  
Reg. No. 28,005

Enclosures

- Terminal Disclaimer
- Courtesy Copy of lists (1)-(7) enclosed with  
September 12, 2000 application transmittal
- IDS and PTO-1449

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